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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,324	01/04/2002	H. William Bosch	029318-0107	2223

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EXAMINER	
HAGHIGHATIAN, MINA	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
10/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/035,324	BOSCH ET AL.	
	Examiner	Art Unit	
	Mina Haghighatian	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 September 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11 and 13-34* is/are pending in the application.

4a) Of the above claim(s) *15-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7, 9-11, 13-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the Amendments and Remarks filed on 09/06/07. Claims 1, 4-7 and 9-11 have been amended and claims 8 and 12 have been cancelled. No new claims have been added. Claims 15-34 remain withdrawn. Accordingly, claims **1-7, 9-11 and 13-14** are under examination.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 9-11 and 13-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wiedmann et al (5,747,001) in view of Desai et al (US 20070117862).

Wiedmann et al teach aerosols containing droplets of an aqueous **dispersion** of nanoparticles of insoluble **beclomethasone** particles having a surface modifier on the surface thereof. Representative examples of surface modifiers include gelatin, bezalkonium chloride, PVA, sorbitans, etc (see col. 3, line 30 to col. 4, line 45). A suitable surfactant is **tyloxapol** (see col. 4, lines 49-60), the particles are preferably less than 400 nm in size, or more preferably less than 250 and most preferably **less than 100 nm** in size (see col. 6, lines 8-15 and col. 10, lines 25-35). The process of making such nanoparticles includes attrition and **filtration** (see col. 7, lines 18-21). It is disclosed that the concentration of the beclomethasone in the liquid medium can vary

from about 0.1 to 60%, and preferably from 5-30% (w/w) (see col. 6, lines 19-22). Weidmann discloses that the surface modifiers can be present in the formulation in an amount from 0.1-90% or preferably from 20-60% based on the total weight of the dry particles (see col. 6, lines 23-28 and col. 10, lines 40-55). Wiedmann lacks teachings on sterile filtration.

Desai et al teach formulations for in vivo delivery of pharmacological agents in which the pharmacologically active agent is delivered in the form of suspended particles. There is also provided, a process of preparing unusually small **nanoparticles** of less than 200 nm in diameter, which can be **sterile-filtered**, through a 0.22 micron filter (see [0051]). Desai et al disclose methods for the preparation of substantially water insoluble pharmacologically active agents for in vivo delivery, said method comprising, combining an organic solvent having said active agent dissolved therein, water, a surfactant and a co-surfactant that spontaneously form a micro-emulsion and removing said organic solvent to yield a suspension of nanoparticles of said active agent in said water (see [0093] to [[0100]). It is further disclosed that insoluble active agents include inhalant corticosteroids such as beclomethasone dipropionate and budesonide (see [0122] and [0146]).

Examples 4, 5 and 8 disclose a nanoparticle formation wherein the dispersion is sterile filtered.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to have implemented the sterile filtration method as taught by Desai et al in the formulations and process of Wiedmann, since Wiedmann teaches filtration of nanoparticles of beclomethasone and tyloxapol. In other words, one of ordinary skill in the art would have been motivated to implement sterile filtration of Desai et al instead of simple filtration of Wiedmann because sterilized formulations are safer and beneficial to recipients. In other words, the claims would have been obvious because the technique for improving a particular product was part of the ordinary skill in the art, in view of the teaching of the technique for improvement in other situations. Specifically, it is shown that sterile filtration of solid dispersions of nanoparticles in liquid mediums is known in the art (as taught by Desai et al). Weidmann teaches the formulations.

Response to Arguments

Applicant's arguments with respect to claims 1-14 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghighatian whose telephone number is 571-272-0615. The examiner can normally be reached on core office hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Mina Haghighatian
Patent Examiner
October 18, 2007